DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 31, 2016

AngioScore, Inc.
c/o Hogan Lovells US, LLP
555 Thirteenth Street NW
Washington, District of Columbia 20004
ATTN: Jonathan S. Kahan

Re: K110767
Trade/Device Name: AngioSculpt® PTA Scoring Balloon Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PNO
Dated: March 18, 2011
Received: March 18, 2011

Dear Mr. Kahan:

This letter corrects our substantially equivalent letter of April 15, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Misti L. Malone -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K110767

Device Name: AngioSculpt PTA Scoring Balloon Catheter

Indications for Use:

The AngioSculpt PTA Scoring Balloon Catheter is intended for dilatation of lesions in the iliac, femoral, ilio-femoral, popliteal, infra popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. Not for use in the coronary or neuro-vasculature.

Prescription Use X AND/OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109) (Per 21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K110767

K110747

APR 15 2011

510(k) SUMMARY

AngioScore AngioSculpt® PTA Scoring Balloon Catheter

1. Submitter's Name / Contact Person

Submitter: AngioScore, Inc.
5055 Brandin Court
Fremont, CA 94538

Contact Person: Kimberley Kline
Regulatory Affairs Manager
Phone: 510.933.7989
Fax: 510.933.7994

Summary Preparation Date: April 11, 2011

2. General Information

Trade Name:	AngioSculpt® PTA Scoring Balloon Catheter
Common / Usual Name:	Angioplasty catheter
Classification Name:	Percutaneous Catheter
Classification Regulation:	21 CFR § 870.1250
Product Codes:	DQY and LIT
Predicate Devices:	AngioSculpt® Scoring Balloon Catheter (K050629, K072225, K080151, K081220, K082059, K091966, K100303)

3. Intended Use / Indications

The AngioSculpt PTA Scoring Balloon Catheter is intended for dilatation of lesions in the iliac, femoral, ilio-femoral, popliteal, infra popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. Not for use in the coronary or neuro-vasculature.

4. Device Description

The AngioSculpt catheter is a standard two-lumen catheter with a scoring balloon near the distal tip. The distal end of the catheter has a conventional nylon-blend balloon with a nitinol scoring element that wraps around the balloon. The scoring element creates focal concentrations of

dilating force which minimizes balloon slippage and assists with luminal expansion of stenotic arteries. The balloon has radiopaque markers to aid in positioning the balloon in the stenosis, and is designed to provide an expandable segment of known diameter and length at a specific pressure.

The modified AngioSculpt PTA catheter has very similar technological characteristics as the cleared AngioSculpt PTA catheter. The modified AngioSculpt PTA Catheter is exactly the same device as the cleared AngioSculpt PTA catheter, except for minor differences to the distal bond and intermediate bond of the 0.018" OTW platform, 20mm balloon length catheters.

5. Summary of Non-Clinical Performance Testing

Design verification testing of the distal and intermediate bonds, manufactured using the modified design and modifications to the manufacturing process, was conducted to verify that the modified bonds meet specifications.

Based on the application of risk analysis and a change impact assessment, the device was evaluated for the following product attributes potentially affected by the design changes and the modifications to the bonding processes:

- Entry Profile (distal bond OD)
- Profile (intermediate bond OD)
- Fatigue Strength
- Bond Tensile Strength
- Visual inspection for distal bond imperfections
- Visual inspection for intermediate bond imperfections

Conclusions

The results of the testing demonstrate that the device meets the acceptance criteria and has substantially equivalent performance to the predicate.

The changes to the distal and intermediate bonds have no impact on all other previously submitted data. The previously submitted data are applicable to the modified AngioSculpt PTA catheter.

6. Substantial Equivalence Comparison

The modified AngioSculpt PTA Catheter has the same intended use and indications for use as the previously cleared AngioSculpt PTA Catheter. In addition, the modified AngioSculpt PTA Catheter has very similar technological characteristics as its predicate. The differences between the current AngioSculpt PTA Catheter and its cleared predicate include minor modifications to the design and manufacturing process of the distal and intermediate bond of the device. These differences do not raise new questions of safety or efficacy, nor substantially

alter the fundamental scientific technology of the device. Testing demonstrates that the modified device meets its specifications with no observations of distal or intermediate bond imperfections, and is substantially equivalent to the cleared AngioSculpt PTA Catheter.

As the AngioSculpt PTA Catheter has the same intended use and indications for use as the predicate, and has substantially similar technological characteristics, and the minor technological differences do not raise new questions of safety or efficacy, the AngioSculpt PTA Catheter is substantially equivalent to the predicate device.